UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/379,540	08/24/1999	SHLOMO BEN HAIM	BIO-76	1397

7590 12/20/2001

AUDLEY A CIAMPORCERO JR
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 089337003

EXAMINER	
GHAFOORIAN, ROZ	
ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 12/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

55

Office Action Summary	Application No.	Applicant(s)	
	09/379,540	HAIM ET AL.	
	Examiner	Art Unit	
	Roz Ghafoorian	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 1999* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Information Disclosure Statement

The information disclosure statement filed 08/24/1999 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 1, 2,12,13, 14,15, 32, 35, 38 rejected under 35 U.S.C. 102(e) as being clearly anticipated by U.S Patent No.6283951 to Flaherty et al. Flaherty discloses

systems and methods that use the cardiovascular system as a conduit to deliver drugs, such as therapeutic drugs, genes, growth factors and the like, directly to selected tissue regions within the body. (Col.1, line 10-15) "Drug" as defined herein includes any therapeutic drugs, genetic materials, growth factors, cells, e.g. myocites, vectors carrying growth factors, and similar therapeutic agents or substances that may be delivered within a patient's body for any therapeutic, diagnostic or other procedure. In one aspect of the present invention, a transvascular catheter system is provided that generally includes a catheter, a drug delivery element, an orientation element, and possibly a puncturing element and/or an imaging element. (Col.3 line 54-62)

The imaging element is an ultrasound transducer within the catheter which preferably including the orientation element which selects tissue region and/or other landmarks within the vessel or the surrounding tissue. Where the puncturing element is a drug delivery needle, the needle may be deployed, penetrating a wall of the blood vessel and entering the tissue region, and the drug may be delivered through a lumen in the needle. (Col.5, lines18-25)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 3 --11 rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty in view of Morocos et al (U.S patent No.5865738). As noted above, the Flaherty reference discloses a drug delivery device, which consists of a catheter, one position sensor, and delivers cells such as myoblasts or myocyte in to the heart chamber. Flaherty, however does not teach a method of assessing the viability of the heart. Morocos discloses a method and apparatus for evaluating the viability of a tissue of interest, particularly that presents as dead but may be merely stunned or hibernating with reduced or no obvious activity, such as contractility (abstract).

This apparatus is carried at the tip of a catheter, which can be guided inside the heart during cardiac catheterization. The new probe allows the physician to: 1) position the probe at a tissue of interest, 2) evaluate the initial state of the tissue, 3) diffuse into the tissue basic ingredients needed for cellular respiration and resulting energy production (oxygen, oxygen-releasing substrates, glucose, low energy phosphates); 4) detect the result of this process by measuring substance uptake, oxygen utilization and/or oxidation reduction (redox) stores of the respiratory enzymes; and 4) optionally detect consequent mechanical activity by ultrasound backscatter technique (in conjunction with a second catheter). (col.9, line 31) This apparatus allows a one to plan in detail (definition of mapping as found in dictionary was plan in detail) where the damaged tissue was located.and when a myocite or a myoblast should be delivered. There for it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combine the two teaching, since according to Morocos cardiologists and cardiac surgeons would both benefit from a procedure which would

identify cardiac tissue which has a good probability of returning to normal function. (Col.5, line 60)

3. Claims18, 19,21-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty as applied to claim1 above, and further in view of German et al U.S Patent No.6258789. As noted above, the Flaherty reference discloses a drug delivery device, which consists of a catheter, one position sensor, and delivers cells such as myoblasts or myocyte in to the heart chamber. Flaherty, however, does not teach the origin of the cell. German discloses cells of a mammalian subject, which are genetically altered to operatively incorporate a gene, which expresses a protein, which has a desired effect. (Abstract). These cells are genetically altered by exposure to a formulation comprising nucleic acids, thereby facilitating expression of a gene encoding a therapeutically effective protein. (Col.3 line 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention as made to have included the teaching of both Flaherty and German, because German simply expands on the origins of the cells in Flaherty teachings.

4. Claims16-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty as applied to claim1 above, and further in view of Tremblay et al U.S Patent No.5833978. As noted above, the Flaherty reference discloses a drug delivery device, which consists of a catheter, one position sensor, and delivers cells such as myoblasts or myocyte in to the heart chamber. Flaherty, however, does not teach the detailed

treatment of the cell prior or after delivery of the cell to the heart. Tremblay, however, discloses a method of pre-treating healthy donor's myoblast cultures with growth or trophic factors like basic fibroblast growth factor (bFGF) on transplantation to subjects suffering of recessive myopathy like muscular dystrophy (Abstract). Tremblay also teaches, basic FGF is thought to regulate myogenesis during muscle development and regeneration in vivo. (Col.3, line 27-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention as made to have anticipated myogenesis and cell fusion when utilizing a growth factor.

5. Claims16, 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty as applied to claim1 above, and further in view of Nabel et al U.S Patent No. 5328470. As noted above, the Flaherty reference discloses a drug delivery device, which consists of a catheter, one position sensor, and delivers cells such as myoblasts or myocyte in to the heart chamber. Flaherty, however, does not teach the detailed treatment of the cell prior or after delivery of the cell to the heart. Nabel discloses a method for the treatment of a disease by site-specifically replacing damaged cells in a patient (col.3 line 30). Nabal also teaches a possible to modulate the animal's immune system. In particular, by transforming cells of an animal, with a recombinant gene, by site-specific or systemic administration it is possible to modulate the animal's immune system to sensitize the animal to the molecule for which the recombinant gene encodes. (col.4, line 10-15). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention as made to have included the teaching of both Flaherty and

Nabel, because Nabel simply expands on the treatment of the cells in Flaherty teachings.

6. Claims 6,7,8, 12,15,16,17, 25-31, rejected under 35 U.S.C. 103(a) as being unpatentable over Flahetry as applied to claim1 above, and further in view of Gambale et al U.S Patent No.6277082. As noted above, the Flaherty reference discloses a drug delivery device, which consists of a catheter, one position sensor, and delivers cells such as myoblasts or myocyte in to the heart chamber. Flaherty, however, does not teach a catheter which utilizes a laser to create a channel at an oblique angel were the said cells would be delivered. Gambale discloses an invention provides devices and methods for detection of ischemic biological tissue by temporarily altering the temperature of the tissue. (Abstract) Gambale also discloses a detection of an ischemic area of tissue may be followed by a treatment, which may include the implantation of an angiogenic implant alone or in conjunction with a therapeutic agent, such as a growth factor to promote angiogenesis or a cell or gene therapy substance to initiate regeneration of the subject tissue. In such cases, the obturator is adapted to penetrate the tissue in order to facilitate the placement of the angiogenic implant into the tissue alternatively the treatment may comprise creation of channels in the ischemic region by mechanical or laser energy.(col. 3 , line 40-50) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention as made to have included the teaching of both Flaherty and Gambale, because according to Gambale if the tissue has remained viable despite the previous deprivation of blood, revascularization, or the restoration of blood flow, to dormant or hibernating tissue can restore the muscle's

normal function. (Col.1, line 5-10) Injection of growth factor into myocardial tissue initiates angiogenesis at that site, which is exhibited by a new dense capillary network within the tissue accurate diagnosis and identification of ischemic areas is essential to proper treatment. (Col.2, Line 5-25)

7. Claim 33, 36, 39 rejected under 35 U.S.C. 103(a) as being unpatentable over Flahery as applied to claim1 above, and further in view of Kramer U.S Patent No.5960796. As noted above, the Flaherty reference discloses a drug delivery device, which consists of a catheter, one position sensor, and delivers cells such as myoblasts or myocyte in to the heart chamber. Flaherty, however, does not teach a catheter with a device capable of providing a pressure burst. Kramer discloses a method of infusion of durg in to the bone maroow. It also teaches a monitoring over pressurization during high-pressure infusions or blocked fluid flow as indicated by absence of anticipated sensor response. These operations could be combined with a microprocessor-controlled system to automatically warn the operator of unsafe or otherwise unsatisfactory conditions. (Col.4, line 40) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention as made to have included the teaching of both Flaherty and Kramer, because according to Kremer this invention helps in monitoring over pressurization.

8. Claims 34, 37, 40 under 35 U.S.C. 103(a) as being unpatentable over Flahery as applied to claim1 above, and further in view of Lemelson U.S Patent No.4578061. As noted above, the Flaherty reference discloses a drug delivery device, which consists of a catheter, one position sensor, and delivers cells such as myoblasts or myocyte in to the heart chamber. Flaherty, however, does not teach a catheter with a retractable needle. Lemelson discloses a catheter with a retractable needle and method are provided for injecting a quantity of a liquid. (Abstract) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention as made to have included the teaching of both Flaherty and Lemelson, because according to Lemelson the needle need to be retractable so that it will not penetrate tissue as the device is worked through the body. (Col.1 line 40)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Ghafoorian whose telephone number is 703-305-2336. The examiner can normally be reached on 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0858 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-5648.

RG
December 13, 2001

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700